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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/055,174	Applicant(s) Btiggs et al.
	Examiner Jennifer Graser	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Election, 4/21/03*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *36-41 and 66-95* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *36-41 and 66-95* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 36-41 and 66-95, in Paper No. 5B is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The disclosure is objected to because of the following informalities:

The Accession No. on page 2, line 29, and page 6, line 23, is missing.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 36-41 and 66-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 66, 67, 71, and 81 are vague and indefinite because they are drawn to a method of inducing immunity to pneumonic pasteurellosis in a mammal through the administration of a bacterium which is claimed by functional properties alone. The claim must provide any

structural properties of the bacterium to be used in the method, such as the structure of its leukotoxin gene, i.e., the location of the deletion, which would allow for one to identify the bacterium without ambiguity. Additional structural description of the bacterium is needed in order to particularly point out and distinctly claim the subject matter which is the invention. The breadth of the claims does not allow for one to understand the metes and bounds of the invention.

Claims 88-95 are vague and indefinite because they are drawn to products comprising a bacterium which is claimed by functional properties alone. The claim must provide any structural properties of the bacterium to be used in the method, such as the structure of its leukotoxin gene, i.e., the location of the deletion, which would allow for one to identify the bacterium without ambiguity. Additional structural description of the bacterium is needed in order to particularly point out and distinctly claim the subject matter which is the invention. The breadth of the claims does not allow for one to understand the metes and bounds of the invention.

Claims 66, 67, 81 and 88-95 are also vague and indefinite because it is unclear how the antibodies neutralize biologically active leukotoxin. The claims should be amended to recite that the "leukotoxin molecule induces antibodies which specifically bind to and neutralize biologically active leukotoxin".

Claims 67-87, 89-91 and 93 are vague and indefinite because the claims recite that the "live form of the lyophilized [or killed or lyophilized and killed] bacterium expresses a form of leukotoxin molecule which induces antibodies which neutralize biologically active leukotoxin". Accordingly, since these methods/vaccines/feed comprise killed bacteria the leukotoxin which is

the active ingredient of the bacterium will not be expressed; therefore, it is unclear how the methods/vaccines/feed function. Clarification is requested.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 36-41 and 66-95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "a method of inducing immunity to pneumonic pasteurellosis in a mammal comprising the steps of administering an isolated live *P.haemolytica* bacterium which expresses no biologically active leukotoxin, expresses a form of a leukotoxin molecule which is a deletion mutant of about 66kDa which lacks amino acids 34 to 378 and which induces antibodies which specifically bind to and neutralize biologically active leukotoxin and contains no foreign DNA", does not reasonably provide enablement for "a method of inducing immunity to pneumonic pasteurellosis in a ruminant comprising the steps of administering an isolated live, or lyophilized or killed or lyophilized and reconstituted *P. haemolytica* which a) expresses no biologically active form of the virulence factor, b) expresses a form of leukotoxin which induces antibodies which neutralize biologically active leukotoxin; and c) contains no non *P.haemolytica* DNA", nor does it enable feed or vaccines comprising said killed, lyophilized, reconstituted and lyophilized bacterium." The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims are drawn to any *"P.haemolytica* leukotoxin molecule which is biologically inactive, induces antibodies which specifically bind to leukotoxin and contains no foreign amino acid sequences"; however, the specification only provides guidance for a specific bacterium expressing a mutant leukotoxin, i.e., a leukotoxin which is 66kDa and lack amino acids 34 to 378. It would take one of skill in the art undue experimentation in order to identify and/or produce a non-toxic *P.haemolytica* which can still produce antibodies which bind to leukotoxin. Applicants have not identified any other mutations which could be made which would produce a leukotoxin with the properties described in the instant. It would take one of skill in the art undue experimentation to perform numerous deletion experiments to obtain a leukotoxin molecule which is inactive yet retains the same immunological characteristics as the native leukotoxin molecule when expressed by a host bacterium administered to a ruminant. The prior art teaches that selective point mutation to one key antigen residue could eliminate the ability of an antibody to recognize this altered antigen. If the range of decreased binding ability after single point mutation of a protein antigen varies one could expect point mutations in the protein antigen to cause varying degrees of loss of function, depending on the relative importance to the binding interaction of the altered residue. Alternatively, the combined effects of multiple changes in an antigenic determinant could again result in loss of function. A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues

could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies in the polyclonal pool. The specification provides no guidance as to what amino acids may be changed without causing a detrimental effect to the leukotoxin to be produced. Further, it is unpredictable as to which amino acids could be removed and which could be added. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of success are limited. Other positions are critical to the protein's structure/function relationship, e.g., such as various positions or regions directly involved in binding, catalysis in providing the correct three-dimensional spacial orientation of binding and catalytic sites. These regions can tolerate only very little or no substitutions. To start with the DNA sequence first, this requires even more work on the part of the skilled artisan. The instant specification only provides guidance and working examples for this one specific bacterium which expresses a leukotoxin with the claimed properties, i.e., a bacterium which is transformed with a gene that expresses a 66kDa leukotoxin molecule which lacks amino acids 34 to 378. The skilled artisan cannot envision the detailed structure of the encompassed bacterium to be used in the methods and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate enablement and written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The composition itself is required. Given the lack of guidance contained in the specification and the unpredictability for determining acceptable amino acid

substitutions, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Additionally, newly presented claims 67-87, 89-91 and 93-95 are drawn to methods of inducing immunity to pneumonic pasteurellosis in a ruminant comprising the steps of administering an isolated live, or lyophilized or killed or lyophilized and reconstituted *P. haemolytica* which a) expresses no biologically active form of the virulence factor, b) expresses a form of leukotoxin which induces antibodies which neu ive leukotoxin; and c) contains no non *P.haemolytica* DNA and feed or vacc killed, lyophilized, reconstituted and lyophilized bacterium. However, the i ly provides examples of vaccines, feed and methods which use a live y the an isolated live *P.haemolytica* bacterium which expresses no biologi , expresses a form of a leukotoxin molecule which is a deletion mutant of about 66kDa which lacks amino acids 34 to 378 and which induces antibodies which specifically bind to and neutralize biologically active leukotoxin and contains no foreign DNA. The specification teaches that it is the mutant leukotoxin which is the active agent which specifically binds to and neutralizes biologically active leukotoxin. In a killed or lyophilized bacterium, the mutant leukotoxin would not be expressed. Accordingly, it is unclear how these killed cells would have the ability to induce immunity to pneumonic pasteurellosis in ruminants. The specification provides no examples using the killed or lyophilized bacterium which are materially different than the live version of the bacterium. The results from the use of the live bacterium do not correlate to the

killed bacterium because the active agent is not expressed in the killed bacterium. The vaccine art is highly unpredictable in the area of prevention of bacterial diseases. Since the specification provides no results except for the use of an isolated live *P.haemolytica* bacterium which expresses no biologically active leukotoxin, expresses a form of a leukotoxin molecule which is a deletion mutant of about 66kDa which lacks amino acids 34 to 378 and which induces antibodies which specifically bind to and neutralize biologically active leukotoxin and contains no foreign DNA, or the isolated mutant leukotoxin molecule of 66kDa, lacking amino acids 34 to 378, claims 67-87, 89-91 and 93-95 are not enabled. A vaccine comprising a killed *P.haemolytica* containing the specified mutant gene, i.e., expresses a leukotoxin lacking amino acids 34 to 378, would appear to be analogous to a vaccine preparation comprising a killed wild-type *P.haemolytica,* which were well known in the art at the time the invention was made, since the killed vaccines would express no leukotoxin and it appears that they would produce the same immune response.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 36-41, 66, 88 and 92 are rejected under 35 U.S.C. 102(a) as being anticipated by . Prideaux et al (WO 97/16531).

Prideaux et al disclose methods for achieving immunity against pneumonic pasteurellosis. They teach a live modified *P.haemolytica* microorganism which produces an Lkt toxin, wherein said Lkt toxin is partially or fully inactivated, but still induces an immune response in an animal that offers cross protection against heterologous challenge with a microorganism which produces the Lkt toxin, i.e., neutralizes biologically active leukotoxin. It is specifically taught that the Lkt structural gene, i.e, LktA gene, may be partially or fully inactivated. This includes an in-frame deletion of the gene. See claim 5 of the reference and page 7, lines 6-10. It is discloses that the vaccine may be administered by any suitable route such as by oral or parenteral administration, including subcutaneously or intradermally (page 12, lines 28-32). The vaccine may be administered to ruminants (see page 12, lines 20-25). The terms "vaccine" and "feed" (claims 88 and 92) are an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The instant claims do not recite a structure for the live bacterium. Since Prideaux et al's bacterium possesses the same function as the bacterium recited in the claims the claims are anticipated by the reference.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 36, 38-41, 66, 88 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potter et al (5,422,110) in view of Briggs et al (5,733,780).

Potter et al disclose DNA constructs which encode an *inactivated* leukotoxin polypeptide operably linked to selected antigen and control sequences which direct the transcription of the constructs so that they can be transcribed and translated in a host cell (col. 2, lines 57-68) and host cells transformed with these cassettes (col. 3, lines 1-2). Potter defines "leukotoxin" to mean "molecules which remain immunogenic yet lack the cytotoxic character of native leukotoxin: and provides several nucleotide and amino acid sequences for these molecules (col. lines 5-15). See column 12, lines 47-60 for a discussion of mutants and/or analogs which may be prepared by deletion or substitution. It is disclosed that depending on the expression system and host selected, the proteins of the present invention are produced by growing host cells transformed by an expression vector wherein the protein of interest is expressed (col. 13, lines 3-10). This reference discloses several nucleotide and amino acid sequences for leukotoxin molecules which remain immunogenic yet lack the cytotoxic character of native leukotoxin (see col.lines 5-15) and the reference specifically discloses expressing them in a host cell. However, the reference does not specifically recite that these host cells can be *P.haemolytica* cells.

Briggs et al disclose techniques for introducing exogenous DNA into *P.haemolytica* to produce site-specific mutations in the bacterium in order to provide live vaccines against

pneumonic pasteurellosis. It is disclosed that live vaccines elicit a stronger cell mediated response in the host than do bacterins (col. 1, lines 39-41). The invention comprises inducing mutations within the DNA of *P.haemolytica* and administering the live, whole cell to a host.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to create recombinant host cells which were transformed with the inactivated leukotoxin and/or an antigen as disclosed by Potter because doing so would allow for production of a vaccine/immunogenic composition which would provide protection against *P.haemolytica* infections without the cytotoxic problems normally associated with wild type leukotoxin and because recombinant host cell vaccines have been well known in the art for many years and because it was well known that live vaccines elicit a stronger cell mediated response in the host than killed vaccines or solely a protein from the bacterium. One of ordinary skill in the art would have expected to obtain a greater immune response to the leukotoxin proteins of Potter by administering the whole cell as evidenced by Briggs. Additionally, the use of a *P.haemolytica* cell as the host cell would have been obvious because Potter discloses that any host cell may be used and because Briggs specifically discloses using a *P.haemolytica* cell which expresses an inactivated, yet antigenic toxin (described by Potter) would have produced a more efficient immune response without the treat of cytotoxicity in the vaccines disclosed by Potter. The fusion partner of Potter et al would be optional since Potter teaches several nucleotide and amino acid sequences for leukotoxin molecules which remain immunogenic yet lack the cytotoxic character of native leukotoxin. Accordingly, it would have been obvious to one of ordinary skill in the art

at the time the invention was made to use solely the inactive leukotoxin in the constructs. The use of a *P.haemolytica* promoter and a *P.haemolytica* host cell would allow for expression of inactive leukotoxin which induces antibodies which would bind leukotoxin yet would contain no non-*P.haemolytica* DNA. The terms "vaccine" and "feed" (claims 88 and 92) are an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

11. Claims 36, 38-41, 66, 88 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cruz et al (Mol.Microbiol., 1990, 4(11): 1933-1939) in view of Briggs et al (5,733,780).

Cruz et al teach a series of internal deletions and amino-proximal deletions in the lktA gene which eliminate the lytic activity of the leukotoxin (abstract and page 1935, column 1). It was discovered that the cell binding domains and lytic domains are separable in the leukotoxin polypeptide. It was found that the plasmids with amino-proximal deletions were found to encode an agglutinating activity. Cruz tested the ability of the cells expressing the mutants to protect cells from lysis by the native leukotoxin. It was found that protection was found to be dependent on the agglutinating activity. Cruz tested the ability of the cells expressing the mutants to protect cells from lysis by the native leukotoxin. It was found that protection was found to be dependent on the agglutinating protein to active toxin, indicating that the mutant toxin may saturate

available leukotoxin binding sites on the cell surface (page 1935, column 2). The protection was not due to the agglutination; however, only the plasmids encoding agglutinating mutants of leukotoxin had protective activity (page 1935, column 2). The reference indicates that deletions more towards the middle of the leukotoxin nucleic acid sequence could not produce leukotoxin which possessed agglutinating activity. However, Cruz et al do not specifically recite using a *P.haemolytica* cell as the host cell and using this bacterium in a method to induce immunity to pneumonic pasteurellosis.

Briggs et al disclose techniques for introducing exogenous DNA into *P.haemolytica* to produce site-specific mutations in the bacterium in order to provide live vaccines against pneumonic pasteurellosis. It is disclosed that live vaccines elicit a stronger cell mediated response in the host than do bacterins (col. 1, lines 39-41). The invention comprises inducing mutations within the DNA of *P.haemolytica* and administering the live, whole cell to a host to protect against pasteurellosis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a *P.haemolytica* host cell in place of an *E.coli* host cell as taught by Cruz et al because one of ordinary skill in the art would have a reasonable expectation that the use of a *P.haemolytica* cell which expresses an inactivated, yet antigenic toxin would have produced a more efficient immune response due the additional presence of other *P.haemolytica* antigens on the cell's surface. Further, although Cruz et al do not specifically recite the amino acids which were deleted or the size of the deletion mutant, Cruz et al does teach that amino-proximal

deletions are the are one would want to delete in order to have production of a protective, non-lytic leukotoxin molecules and one of ordinary skill in the are would therefore have been motivated to delete this region, i.e., amino acids 34 and larger (yet not too far down since this took away the protective activity). Additionally, the size of the deletion mutant in claim 4 is consistent with what one of ordinary skill in the art would expect for the deletions disclosed by Cruz et al. Accordingly, the use of a *P.haemolytica* cell for the mutants taught by Cruz in Briggs would have been obvious and it would have created a more efficient vaccine against pasteurellosis. The terms "vaccine" and "feed" (claims 88 and 92) are an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The instant claims do not recite a structure for the live bacterium. Since the bacterium disclosed by the prior art reference possesses the same function as the bacterium recited in the claims the claims are unpatentable.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 36-41 and 66-95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. U. S. Patent No. 6,495,145. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Patented claims are a species encompassed within the genus of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented..

14. Claims 36-41 and 66-95 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-29 of copending Application No. 09/736,169. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 09/736,169 are a species encompassed within the genus of the instant claims. Although the method claims of Application No. 09/736,169 specify that the intended target of the method is a mammal wherein the instant claims recite a ruminant, since a ruminant is a mammal the scope of the claims is not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JENNIFER E. GRASER
PRIMARY EXAMINER
5/18/03